

Kansas Department of Health and Environment
Permanent Regulation

28-15-35. Conditions of accreditation. (a) Definitions.

(1) "Accreditation" means the issuance of a document by the secretary attesting to the fact that a laboratory meets the minimum requirements specified in K.A.R. 28-15-35, 28-15-36, 28-15-36a, and 28-15-37. For the purposes of this article, the terms "accreditation" and "certification" are equivalent.

(2) "Accredited," when used to describe a laboratory, means that the laboratory meets all of the requirements for accreditation as specified in K.A.R. 28-15-35, 28-15-36, 28-15-36a, and 28-15-37.

(3) "Accrediting authority" means a territorial, state, federal, or international governmental agency that has responsibility and accountability for environmental laboratory accreditation and that grants accreditation.

(4) "Analyst" means a person who performs the analytical methods and associated techniques and who is responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.

(5) "Clean water act" and "CWA" mean U.S. public law 92-500, as amended by public law 92-217, public law 95-576, public law 96-483, and public law 97-117, and 33 U.S.C. 1251 et seq., as in effect on February 4, 1987, which governs water pollution control programs.

(6) "Denial" means the department's refusal to accredit a laboratory after submission of an application.

(7) "Department" means the Kansas department of health and environment.

(8) "EPA" means the U.S. environmental protection agency.

(9) "Field laboratory" means any Kansas environmental laboratory performing compliance analyses limited to one or more of the following parameters:

- (A) Chlorine;
- (B) dissolved oxygen;
- (C) hydrogen ion (pH);
- (D) sulfite;
- (E) temperature; or
- (F) turbidity.

(10) "Interim accreditation" means accreditation issued for either of the following:

(A) An additional parameter utilizing a technology not previously inspected by the laboratory accreditation officer and for which the laboratory meets all other accreditation requirements including acceptable proficiency testing studies, if available; or

(B) a field laboratory before inspection.

(11) "Laboratory" means a legally identifiable facility performing environmental analyses in a controlled and scientific manner.

(12) "Laboratory accreditation officer" means any person determined by the secretary to have adequate credentials to evaluate laboratories supplemented by

successful completion of the EPA drinking water laboratory accreditation officers' training course, nationally approved assessor training courses, and refresher training courses.

(13) "Laboratory technical director" means a person whose functions are to direct technical personnel and evaluate the quality of test procedures performed in the laboratory.

(14) "Parameter" means any chemical or physical substance for which analysis is performed.

(15) "Parametric group" means organic compounds for which analysis is performed by utilizing a single method.

(16) "Proficiency testing sample" and "PT" mean a sample the composition of which is unknown to the analyst. The PT samples are used to test whether or not the laboratory can produce analytical results within specific performance limits.

(17) "Reciprocity" means the secretary's recognition of the validity of the accreditation granted by another accrediting authority, in order to issue Kansas accreditation based upon the evaluation conducted by that accrediting authority.

(18) "Resource conservation and recovery act" and "RCRA" mean 42 U.S.C. 6921, as amended by the solid waste disposal act of 1980, public law 94-482, as in effect on October 21, 1980, and as amended by the hazardous and solid waste act of 1984, public law 96-616, as in effect on November 8, 1984, which governs solid and hazardous waste programs.

(19) "Revocation" means the withdrawal of a laboratory's accreditation.

(20) "Safe drinking water act" and "SDWA" mean 42 U.S.C. § 300f et seq., as in effect on August 6, 1996, which governs drinking water programs.

(21) "Secretary" means the secretary of the Kansas department of health and environment.

(22) "Suspension" means the temporary removal of a laboratory's accreditation for a period of time that shall not exceed six months.

(23) "Supplemental accreditation" means accreditation based upon state-of-the-art technology for which the EPA has not given method approval and for which monitoring is required by the department.

(b) The requirements for applying for and maintaining accreditation shall be as follows:

(1) A complete application shall be submitted on forms provided by the department.

(2) Each laboratory, to maintain uninterrupted accreditation, shall file an application for renewal at least 60 calendar days before the current accreditation expires.

(3) Each applicant shall be subject to the payment of fees as specified in K.A.R. 28-15-37.

(4) When applications are submitted by accredited laboratories requesting accreditation for additional parameters, the expiration date for the additional accreditation shall be the same date indicated on the certificate currently in effect for that laboratory. Additional fees shall be assessed for each additional parameter or parametric group as specified in K.A.R. 28-15-37.

(c) Scope of accreditation. Laboratories may be accredited for any of the following:

(1) Drinking water (SDWA);
(2) wastewater (CWA);
(3) solid and hazardous waste (RCRA); or
(4) field laboratory. Accreditation of field laboratories shall be limited to the parameters specified in paragraph (a)(9) of this regulation.

(d) On-site assessment.

(1) Each on-site assessment of a laboratory shall be conducted by a laboratory accreditation officer at least once every two years. Each on-site assessment shall be conducted to determine whether the laboratory meets the minimum requirements for accreditation as specified in K.A.R. 28-15-35 and 28-15-36.

(2) Each on-site assessment of a field laboratory shall be conducted by a laboratory accreditation officer at least once every three years. On-site assessments shall be conducted to determine whether the laboratory meets the minimum requirements for accreditation as specified in K.A.R. 28-15-35 and 28-15-36a.

(3) Additional on-site assessments may also be performed to resolve problems indicated by deficiencies from proficiency testing, deficiencies from prior on-site assessments, or changes that an accredited laboratory makes in location, personnel, or methodology. Other on-site assessments may be conducted to resolve complaints.

(4) If deficiencies are identified during the on-site assessment, a deficiency report shall be submitted to the laboratory by the department. The laboratory shall respond to the deficiency report with corrective action within 30 days of receiving the deficiency report. If corrective action is considered not acceptable by the laboratory accreditation officer, the laboratory shall have an additional 30 days after notification of nonacceptance to submit a revised plan for corrective action. Failure to comply with this requirement shall result in denial or suspension of accreditation as established in paragraphs (g)(1), (g)(2), and (g)(3) of this regulation.

(e) Proficiency testing. For initial and continuing accreditation, each laboratory, excluding field laboratories, shall participate in proficiency testing studies obtained from a nationally accredited proficiency test provider. Each laboratory shall demonstrate the successful performance of each test method for each parameter for which the laboratory seeks or maintains accreditation. Laboratories shall be permitted to report multiple results for the same parameter from one PT sample by using more than one method.

(1) For initial accreditation, the laboratory shall meet the following requirements:

(A) Successfully complete two proficiency testing studies out of the three most recent rounds attempted; and

(B) schedule proficiency testing studies at least 15 days after the closing date of the previous study analyzed by the laboratory. The most recent three rounds attempted shall have occurred within 18 months of the date the laboratory submitted an application for accreditation. A result shall be considered unacceptable if the laboratory reports values for a parameter outside of the acceptance limits.

(2) (A) For continuing accreditation, the laboratory shall meet the following requirements:

(i) Participate in a proficiency testing study twice per year. The completion dates of successive PT studies shall be approximately six months apart; and

(ii) maintain a performance history of at least two acceptable proficiency testing studies out of the three most recent studies. A result shall be considered unacceptable when either the laboratory reports values outside of the acceptance limits or the laboratory fails to participate in a study.

(B) Failure to maintain the acceptable performance history as specified in paragraph (e)(2)(A)(ii) shall result in suspension of the method related to the affected parameter.

(C) A laboratory may elect to analyze a remedial proficiency testing sample after obtaining unacceptable results. The remedial sample shall be scheduled at least 15 days after the closing date of the previous study analyzed by the laboratory. The remedial sample shall be considered part of the laboratory's corrective action. The result shall count as part of the historical two-out-of-three performance criteria. If the result from the remedial sample is unacceptable, the laboratory shall be subject to suspension of the method related to the affected parameter.

(3) After loss of accreditation of a parameter due to nonacceptable performance, the laboratory shall complete two acceptable proficiency testing studies out of the three most recent studies attempted for the failed parameter before accreditation may be reinstated. Each study shall be scheduled at least 15 days after the closing date of the previous study analyzed by the laboratory.

(4) Proficiency test providers shall report laboratory results for proficiency test samples in the format listed in "proficiency testing electronic data formats," published April 2003 by the department and hereby adopted by reference.

(f) Notification of accreditation. A certificate shall be issued by the secretary to each laboratory satisfactorily meeting all requirements of K.A.R. 28-15-35, 28-15-36, 28-15-36a, and 28-15-37. The parameters or parametric groups for which the laboratory is accredited shall be noted. An accreditation number shall be assigned to each accredited laboratory and shall be included on the certificate. The certificate shall be issued for a 12-month period. The accreditation period may vary from the 12-month period for administrative reasons.

(g) Denial, suspension, or revocation of accreditation.

(1) Denial of accreditation. Laboratory accreditation shall be denied in part or in total for any of the following reasons:

(A) Failure to submit a complete application;

(B) failure to meet the personnel requirements as specified in K.A.R. 28-15-36 and K.A.R. 28-15-36a;

(C) failure to successfully analyze and report proficiency testing samples as required in subsection (e) of this regulation;

(D) failure to demonstrate to the laboratory accreditation officer that the laboratory meets the required standards for accreditation, based upon an on-site assessment;

(E) failure to respond to the deficiency report with acceptable corrective action after an on-site assessment within the time period established in paragraph (d)(4) of this regulation;

(F) failure to implement corrective action;

(G) misrepresentation or omission of material facts;

- (H) denial of entry during normal business hours for an on-site assessment;
 - (I) failure to pay the required fees as established in K.A.R. 28-15-37;
 - (J) failure to ensure that essential laboratory personnel are available for participation, as needed, for the satisfactory completion of an on-site assessment;
 - (K) any prior sustained charges of administrative violations of state or federal laws and regulations related to the provision of environmental laboratory services or reimbursement for these services, against the owner or owners or laboratory technical director or directors, individually or jointly, or against any laboratory owned or directed by these individuals; or
 - (L) conviction for a crime that is related to environmental laboratory services and involves theft or fraud.
- (2) Accreditation after denial.
- (A) Accreditation shall not be granted until a laboratory has demonstrated to the laboratory accreditation officer that the deficiencies that caused the denial have been corrected.
- (B) If the laboratory is not successful in correcting the deficiencies that caused the denial, the laboratory shall wait six months before submitting a new application.
- (C) After denial of accreditation in part, the laboratory shall reapply for accreditation of the affected parameters. After denial of accreditation in total, the laboratory shall submit a complete application to the department.
- (3) Suspension of accreditation. Any accredited laboratory's accreditation may be suspended in part or in total for any of the following reasons:
- (A) Failure to notify the laboratory accreditation officer in writing within 30 days of changes in ownership, laboratory personnel, laboratory location, or methods that involve a change in technology or instrumentation;
- (B) failure to successfully analyze and report proficiency testing samples as required in subsection (e) of this regulation;
- (C) failure to respond to the deficiency report with acceptable corrective action after an on-site assessment;
- (D) failure to respond to the deficiency report after an on-site assessment within the time period established in paragraph (d)(4) of this regulation; or
- (E) failure to implement corrective action after an on-site assessment.
- (4) Accreditation after suspension.
- (A) Accreditation after suspension shall not be granted until a laboratory has demonstrated to the laboratory accreditation officer that the deficiencies that caused suspension have been corrected.
- (B) After suspension of accreditation in part, the laboratory shall reapply for accreditation of the affected parameters. After suspension of accreditation in total, the laboratory shall submit a complete application to the department.
- (C) If the laboratory does not correct the deficiencies that caused the suspension within six months, the laboratory accreditation shall be revoked in part or in total.
- (5) Revocation of accreditation.
- (A) An accreditation may be revoked in part or in total if it is determined that there has been any of the following:
- (i) Failure to maintain compliance with K.A.R. 28-15-35, 28-15-36, 28-15-36a, and 28-15-37;

(ii) reporting, as official compliance data, any parameter or analytical result for which accreditation has not been obtained;

(iii) failure to respond to the deficiency report with acceptable corrective action after an on-site assessment;

(iv) failure to respond to the deficiency report after an on-site assessment within the time period established in paragraph (d)(4) of this regulation; or

(v) failure to implement corrective action after an on-site assessment.

(B) An accreditation may be revoked in total if it is determined that there has been any of the following:

(i) Misrepresentation or omission of material facts;

(ii) failure to participate in proficiency testing studies as required in subsection (e) of this regulation;

(iii) denying entry to a laboratory accreditation officer during the laboratory's working hours;

(iv) failure to ensure that essential laboratory personnel are available for participation, as needed, for the satisfactory completion of an on-site assessment;

(v) any prior sustained charges of administrative violations of state or federal laws and regulations related to the provision of environmental laboratory services or reimbursement for such services, against the owner or owners or laboratory technical director or directors, individually or jointly, or against any laboratory owned or directed by these individuals; or

(vi) conviction for a crime that is related to environmental laboratory services and involves theft or fraud.

(6) Accreditation after revocation.

(A) After revocation, accreditation shall not be granted until a laboratory has corrected the reason for revocation and has met all the requirements of the revocation order.

(B) After revocation of accreditation in part, the laboratory shall reapply for accreditation of the affected parameters. After revocation of accreditation in total, the laboratory shall submit a complete application to the department.

(h) Analytical results obtained after an accreditation has been suspended or revoked shall not be submitted to the department as official compliance data.

(i) Reciprocity.

(1) Establishment of reciprocity for the accreditation of laboratories located outside of the state of Kansas. Laboratories located outside of the state of Kansas may be accredited by the department, if the laboratory is accredited by a national environmental laboratory accrediting authority that the secretary recognizes as having standards equivalent to those standards established in this regulation and K.A.R. 28-15-36.

(2) Each out-of-state laboratory shall submit an application to the department with a copy of the current certificate issued by the primary accrediting authority or authorities, and the accreditation fees specified in K.A.R. 28-15-37.

(3) Laboratories located outside of Kansas shall not be approved as field laboratories.

(4) The laboratory shall be accredited only for the requested parameters for which it holds accreditation from its primary accrediting authority or authorities. The laboratory

shall be accredited by the department for only parameters and methods included in the Kansas scope of accreditation.

(5) In lieu of reciprocity, any out-of-state laboratory may apply for and receive accreditation from the department if all of the following criteria are met:

(A) The laboratory is located within 25 miles of the Kansas border.

(B) The laboratory is performing laboratory services for its own company facility located within the state of Kansas.

(C) The laboratory meets all other requirements for accreditation as specified in this regulation.

(j) Laboratory withdrawal of accreditation. Any laboratory may withdraw its application for accreditation at any time during the accreditation process. Any laboratory may withdraw from accreditation at any time during the accreditation period. In both cases, each laboratory shall notify the department in writing. The fees submitted to the department up to the time of the notification shall not be refunded, as specified in K.A.R. 28-15-37.

(k) The change in legal status, ownership, or location of an accredited laboratory.

(1) Each accredited laboratory shall notify the department, in writing, of any change in legal status, ownership or location, or any combination of these, within 30 calendar days of the change.

(2) Accreditation shall be transferred if the change in legal status or ownership of the accredited laboratory does not affect the laboratory's staff, equipment, and organization.

(3) Accreditation shall not be transferred if the change in legal status or ownership of the accredited laboratory affects the laboratory's staff, equipment, and organization. The laboratory shall be required to apply for accreditation as specified in subsection (b) of this regulation.

(4) Any change in the legal status, ownership, or location, or any combination of these, may require an on-site assessment of the laboratory by a laboratory accreditation officer.

(5) If a change in ownership occurs, all records and analyses that have been performed and that pertain to accreditation shall be retained for a minimum of five years and shall be subject to inspection by the department during this period without prior notification to the laboratory. (Authorized by K.S.A. 65-1,109a; implementing K.S.A. 65-1711 and 65-1,109a; effective, E-79-14, June 23, 1978; effective May 1, 1979; amended May 1, 1983; amended May 1, 1986; amended May 1, 1988; amended Jan. 24, 1994; amended May 25, 2001; amended March 26, 2004.)

28-15-36. Requirements for accreditation of laboratories other than field laboratories. The minimum requirements for approval of environmental laboratories shall be those listed in "standards for accreditation of environmental laboratories," including appendix A, published February 2004 by the department and hereby adopted by reference. (Authorized by K.S.A. 65-1,109a; implementing K.S.A. 65-1711 and 65-1,109a ; effective, E-79-14, June 23, 1978; effective May 1, 1979; amended May 1, 1983; amended May 1, 1986; amended May 1, 1988; amended Jan. 24, 1994; amended May 25, 2001; amended March 26, 2004.)

28-15-36a. Requirements for accreditation of field laboratories. (a) Accreditation of a field laboratory shall be granted only to those laboratories performing environmental analyses limited to one or more of the following parameters:

- (1) Chlorine;
- (2) dissolved oxygen;
- (3) hydrogen ion (pH);
- (4) sulfite;
- (5) temperature; or
- (6) turbidity.

(b) Personnel. Personnel performing analytical procedures shall meet the following minimum qualifications:

- (1) A high school diploma or equivalent;
- (2) knowledge of the use of analytical equipment and support equipment used for the analysis of the parameters listed in subsection (a) of this regulation; and
- (3) one month's experience in performing the analyses being considered for approval.

(c) Supplies, reagents, standards, and equipment.

- (1) All items necessary for the performance of the analyses shall be available.
- (2) Reagents and standards shall not exceed their expiration date.
- (3) Equipment shall be properly maintained and in working order.
- (4) Automated on-line equipment shall be maintained and calibrated according to manufacturer's instructions. The calibration and maintenance of automated equipment shall be documented.

(d) Analytical methods. Drinking water samples shall be analyzed in accordance with methods approved by the laboratory accreditation officer as required by the safe drinking water act. Environmental water samples analyzed under the clean water act shall be analyzed in accordance with methods approved by the laboratory accreditation officer as required by the clean water act. Environmental samples analyzed under the resource conservation and recovery act shall be analyzed in accordance with methods approved by the laboratory accreditation officer as required by the resource conservation and recovery act.

(e) Sample collection and handling. All samples collected for field laboratory analysis shall be analyzed immediately after collection or on-site. Temperature shall be read at the sample site.

(f) Quality assurance. Each field laboratory shall implement and maintain a detailed,

written standard operating procedure for collection, analysis, reporting, and data handling.

(g) Data handling.

(1) All records relating to data reported for regulatory compliance purposes shall be retained by the laboratory for at least five years. This requirement shall include the following if applicable:

- (A) Calibration or standardization information, or both;
- (B) quality controls, including standards and duplicates;
- (C) calculations;
- (D) sampling and analytical information; and
- (E) reports.

(2) The sampling and analytical data to be retained shall include the following:

- (A) The date, time, and location of sampling and analysis;
- (B) the name of the person collecting the sample;
- (C) the name of the analyst; and
- (D) the type of analysis, method utilized, and results.

(h) Each field laboratory shall notify the accreditation officer in writing within 30 days of changes in analytical equipment, personnel, facility location, facility name, or facility ownership. If changes in personnel take place, the field laboratory shall be responsible for the placement of individuals meeting the qualifications requirements specified in subsection (b) of this regulation.

(Authorized by K.S.A. 65-1,109a; implementing K.S.A. 65-1711, K.S.A. 65-1,109a, K.S.A. 1999 Supp. 65-3406 and 65-3431, and K.S.A. 65-34,105; effective Jan. 24, 1994; amended May 25, 2001.)

28-15-37. Fees. (a) The environmental laboratory accreditation application fee shall be \$150.00 for each scope of accreditation.

(b) The fees specified in subsection (a) of this regulation shall be submitted with the application forms provided by the Kansas department of health and environment.

(c) Upon receipt and approval of the application, a statement of accreditation fees shall be calculated and issued to the laboratory, by the department, as follows:

(1) For each scope of accreditation, excluding field laboratory accreditation, the annual fee shall be \$30.00 for each individual parameter and \$50.00 for each parametric group to a maximum of \$800.00.

(2) The fee for microbiology shall be \$200.00.

(3) The fee for biomonitoring shall be \$200.00.

(4) For field laboratory certification, the fee for each parameter shall be \$90.00.

(d) A fee of \$50.00 shall be assessed for each parameter and parametric group for each scope of accreditation requested as an addition during the accreditation period. This fee shall be assessed in addition to any maximum limit.

(e) (1) The accreditation fee for laboratories accredited by reciprocity shall be as follows:

(A) \$275.00 for each scope of accreditation if the laboratory requests one to 10 parameters or parametric groups, or both;

(B) \$600.00 for each scope of accreditation if the laboratory requests 11 to 20 parameters or parametric groups, or both; and

- (C) \$1,000.00 for each scope of accreditation if the laboratory requests more than 20 parameters or parametric groups, or both.
- (2) All fees shall be submitted with the application forms provided by the department.
- (3) An additional fee of \$50.00 shall be assessed for each parameter and parametric group for each scope of accreditation requested as an addition during the accreditation period.
- (f) All fees shall be remitted in full before the issuance of the certificate. Fees shall not be refunded except in the case of overpayment. Payment of fees shall be made to the Kansas division of health and environmental laboratory. (Authorized by and implementing K.S.A. 65-1,109a; effective, E-79-14, June 23, 1978; effective May 1, 1979; amended May 1, 1986; amended Jan. 24, 1994; amended May 25, 2001.)